A I D S
TREATMENT
N E W S

Issue Number 385
November 22, 2002
Published 18 times a year by
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AIDS Treatment News
1233 Locust St., 5th floor

Contents

AIDS Treatment News

Subscription and Editorial Office:
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Statement of Purpose:
AIDS Treatment News reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations that work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

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New Guidelines on Metabolic Complications of HIV and Antiretroviral Treatment

On November 1 a panel of 12 leading experts on metabolic complications of HIV and antiretroviral treatment published guidelines for managing these complications, and a review of what is already known[1]. The panel looked at glucose intolerance and diabetes, lipid abnormalities such as high triglycerides, body fat distribution changes, lactic acidemia, and bone problems (both osteonecrosis and osteopenia). Guidelines were accepted by consensus of the full panel -- which was funded by the International AIDS Society--USA (not to be confused with the International AIDS Society, a different organization).

In the absence of urgently needed studies to get better treatment information, "the panel recommends routine assessment and monitoring of glucose and lipid levels and assessment and monitoring of lactic acidemia and bone abnormalities if clinical signs or

symptoms are detected. With the exception of body fat distribution abnormalities, specific treatments for these complications are also recommended." Changes in antiretroviral therapy are also suggested, to avoid drugs believed to contribute to the patient's problems.

A copy of the guidelines is available online at:
http://www.iasusa.org/pub/metcomp.html.

References

1. Schambelan M, Benson C, Carr A, and others. Management of metabolic complications associated with antiretroviral therapy for HIV-1 infection: Recommendations of an International AIDS Society-USA panel. *JAIDS (Journal of Acquired Immune Deficiency Syndromes)*. November 2002; volume 31, pages 257-275, http://www.iasusa.org/pub/metcomp.html.

Nevirapine Patient Assistance Program: Model for Better Administration?

Comment by John S. James

The new Boehringer Ingelheim patient assistance program for nevirapine for U.S. residents may be an improvement over other programs, in that it streamlines the paperwork and administration. A patient applies once for a year -- by sending a one-page application plus proof of income. A new foundation set up by Boehringer Ingelheim promises a response in two days. Then the patient picks up the drug four times per year at the doctor's office. At the end of the year the patient can apply again for the next year -- and will be sent a reminder to do so.

It seems that the doctor doesn't have to do burdensome paperwork for this program -- only write the prescription, and hold the medicine package for the patient four times per year. This should prevent a major problem for medical staffs, and open the program to more people in public clinics.

However, the income eligibility level for nevirapine is calculated differently than for the company's non-HIV drugs, for reasons that are not clear. What should be done instead is to have uniform income levels but allow patients to deduct out-of-pocket medical expenses in meeting the income requirement.

A bigger problem may be in the interpretation of, "Be ineligible for prescription assistance through Medicaid." If a patient is eligible for Medicaid prescription coverage but that coverage does not include nevirapine, does he or she just have to do without AIDS treatment? No one eligible for Medicaid could pay for this drug out of pocket, and public programs are increasingly running out of money.

We believe the important advance here is that this program could work efficiently. Many other patient-assistance programs seem designed to get the drug only to those who have enough of a support network around them to possibly make an issue in the media if they don't get treated, while limiting expenses by denying treatment to others. The very paperwork used to restrict those programs makes them expensive to run. But this new program

could control costs by delivering drug efficiently to patients who have no other way to get it, at little cost to the company.

For more information or to apply, visit:
http://us.boehringer-ingelheim.com/about/philanthropy/Patient_Assistance_Program.html
(note: there is no carriage return or space between the two lines above).

Heart-Disease Risk and C-Reactive Protein

by John S. James

In an important study reported this month, in which almost 28,000 healthy U.S. women were followed for eight years, the level of C-reactive protein, a marker of inflammation, was a better predictor than LDL cholesterol of first heart attack or related disease[1]. And there was almost no correlation between the two markers (both blood tests) -- meaning that these tests are finding different at-risk populations, and using both together would be a better predictor than using either alone. Smaller studies have already reported that high C-reactive protein was associated with heart attacks, strokes, and artery disease; the new study confirmed those findings with better data.

C-reactive protein is easy to measure, but this test is not yet generally used in clinical practice. Also, it has not been proven that interventions to reduce the inflammation will lower the risk of disease, although this appears likely. The authors conducted an earlier study[2] and recommend a larger trial of statins for this purpose.

These studies did not involve HIV. However, standard guidelines for lowering heart risk are often used in HIV treatment. And inflammation might be a greater problem in persons with HIV disease than in the general population.

The HIV community should follow this developing research (as well as other experimental tests for measuring heart risk, such as homocysteine levels). Some HIV-specific research would be easy to do -- for example, testing whether certain populations have a higher level of C-reactive protein would require only one blood sample and laboratory test from each member of a cohort. Perhaps AIDS medicine could be a leader in bringing the new information into clinical practice.

References

1. Ridker PM, Rifai N, Rose L, Buring JE, and Cook NR. Comparison of C-reactive protein and low-density lipoprotein cholesterol levels in the prediction of first cardiovascular events. *New England Journal of Medicine.* November 14, 2002; volume 347, number 20, pages 1557-1565.

2. Ridker PM, Rifai N, Clearfield M, and others. Measurement of C-reactive protein for the targeting of statin therapy in the primary prevention of acute coronary events. *The New England Journal of Medicine.* June 28, 2001; volume 344, pages 1959-1965.

Vaccine Against Three

Kinds of HIV Begins Human Tests

The new Vaccine Research Center at the U.S. National Institute of Allergy and Infectious Diseases is starting the first human trial of its vaccine candidate, developed to target HIV clades (subtypes) A, B, and C. Together these subtypes are responsible for about 90% of the world's AIDS epidemic (clade B causes almost all of the infections in the U.S.). Also, it might be more difficult for HIV to develop mutations to escape control by a multiclade vaccine, since it targets the virus in different ways.

Fifty healthy HIV-negative volunteers between 18 and 40 are needed for the first trial, which will be conducted at the National Institutes of Health in Bethesda, Maryland. This placebo-controlled trial will check for safety and also for immune responses to HIV. Later trials will run in several U.S. sites, as well as in Haiti and South Africa.

For more information about the trial, including ways to volunteer, call 1-866-833-LIFE (5433), email vrcforlife@mail.nih.gov, or visit: http://www.niaid.nih.gov/vrc or http://www.clinicaltrials.gov.

Prevention: New Approach Will Test Tenofovir for Persons at High Risk

by John S. James

In a new approach to HIV prevention, the Bill & Melinda Gates Foundation will fund a multi-national trial of the antiretroviral drug tenofovir, taken orally once daily by HIV negative persons at high risk, to see if it can prevent HIV infection. The study, by Family Health International, will take three years, and will focus on sexually active adults in countries with high HIV incidence. If it works, this method could be particularly important for women who cannot negotiate condom use or other ways of protecting themselves.

Dr. Helene Gayle of the Bill & Melinda Gates Foundation noted that experience in using antiretrovirals to protect healthcare workers exposed to HIV, and infants exposed during childbirth, offered hope that it might be possible to prevent sexual transmission as well.

Comment

This study is important because it could open a new front in HIV prevention -- and provide a woman-controlled protection method before microbicides or vaccines are available. Animal studies have suggested that the drug may prevent infection. And tenofovir, approved for over a year in the U.S. for use in HIV treatment, has fewer side effects than other antiretrovirals, so it may be acceptable to persons at high risk but not already infected.

U.S. AIDS Research Needs Tissue Donations

Patients and physicians should know that researchers working on at least a dozen projects funded by the U.S. National Institutes of Health need tissue from persons with HIV for medical research. This includes important studies of viral reservoirs, as well as research into genes that influence how HIV causes AIDS in some but not all individuals, and other questions about how the virus acts in the body. Sometimes tissue removed in biopsies or surgeries is enough. But sometimes the organs and tissues needed can only be collected after death.

In both cases the patient must give consent in advance. For example, when a patient consents to surgery that may result in tissue that would be discarded, the doctor can ask about interest in donating it for medical research.

NIAID (the U. S. National Institute of Allergy and Infectious Diseases, which does most of the AIDS research at the National Institutes of Health) asked the National Disease Research Interchange (NDRI) to collect the tissue needed. NDRI, a nonprofit organization headquartered in Philadelphia, has contracts with physicians and hospitals throughout the country to obtain and properly preserve the tissue and make sure that it reaches qualified researchers. NDRI has been providing tissue for cancer and other disease research for over 20 years and has now started an HIV program. NDRI is not a tissue bank (although it has freezers and can prepare and store tissue in special circumstances); instead, it facilitates arrangements for the tissue to reach the researcher in a timely fashion and in proper condition for the study.

Not everyone's tissue can be used; each research project has its own requirements. Inclusion of a person's tissue often depends on his or her medical condition. For example, at this time (November 2002) researchers most need tissue from persons who were on HAART and asymptomatic, but died in an accident or other cause unrelated to HIV. Research requirements change with the different projects and cannot be predicted in advance. But NDRI would like to hear from anyone who is HIV positive and willing to donate -- either after surgery, or in case of death -- and can answer questions about current needs and research projects.

Persons volunteering to donate in case of death are strongly urged to explain their wishes to their families. Even if a potential donor has consented, his or her family can refuse and overrule their decision.

U.S. residents with HIV who might consider tissue donation, or HIV physicians, can contact NDRI at 800-222-6374 extension 237 for more information. Or check http://www.ndri.com for information about NDRI.

Call for U.S. Action on AIDS, Washington DC November 26

ACT UP and several co-sponsors have called for a peaceful protest at the White House on November 26, less than a week before World AIDS Day, to demand Federal action against AIDS in the U.S. and worldwide. Demonstrators will meet at noon at McPherson

Square, 15th & Eye Streets NW, and march to the White House a few blocks away. Organizers want the Administration to act on the "Saving Families and Communities" initiative recently endorsed by nearly 300 organizations around the world.

The sponsoring organizations are ACT UP New York, ACT UP Philadelphia, Health Gap, African Services Committee, Housing Works, and NYC AIDS Housing Network. Free buses will be available from several New York locations and from downtown Philadelphia.

For more information visit http://www.healthgap.org/WAD.html or email Paul Davis in Philadelphia, pdavis@healthgap.org, or Sharonann Lynch in New York, salynch@healthgap.org.

Drug Patents and Developing Countries: Problems Remain

by John S. James

Despite a widespread and growing consensus that drug patents should not continue to block access to treatment in poor countries, this issue remains. Two recent examples:

* In Sydney, Australia, 25 countries met to work out a compromise on drug exports to take to the 140 member countries of the World Trade Organization (WTO). The problem that prompted the meeting is that while a country can issue a compulsory license if necessary for its domestic use (manufacturing the drug and paying a small royalty to the patent holder), current rules did not make clear that any other country could export the drug to them. So countries like India or Brazil could issue a compulsory license to manufacture patented drugs for their own use -- but countries that could not manufacture the drugs internally could not obtain them this way. This problem will become critical in 2006, when India and other generic drug-manufacturing countries are required to change their patent laws to the U.S./European system to comply with WTO rules.

When the meeting ended on November 15, Oxfam and MSF (Doctors Without Borders) jointly issued a press release calling the Sydney summit a step back for access to medicines. A key problem with the rules adopted is that the exporting country (as well as the importing country) would have to issue a compulsory license. "This makes the needy importing country unacceptably dependent on the political will of another government, and increases the administrative burden. Potential suppliers would also be under enormous pressure from industrialized countries such as the US and EU not to help out." Compulsory licenses for a pharmaceutical have seldom if ever been issued.

The day the Sydney meeting began, a *Washington Post* editorial noted, "From a policy point of view, there is no good argument for allowing patents to restrict access to medicine in poor countries and those just climbing out of poverty; patents generally make sense only in richer countries, where consumers can afford the new therapies produced in response to the incentive of patent-protected profits." ("Drugs for the Poor," *Washington Post*

editorial, November 14).

Note Nov. 22: A week after Sydney we are hearing that there was no meeting of the minds, that reports of an informal consensus were exaggerated. The U.S. and European Union want more restriction against overriding pharmaceutical patents in developing countries for public health, while poor countries in Africa and elsewhere want less. And more than a hundred countries that must agree to a final WTO treaty were not in Sydney at all.

* In Nigeria, activists protested a meeting to be held November 20-22 in Abuja, Nigeria, to "decide on the final draft for Nigeria's Intellectual Property (IP) law, which will, among other things, regulate importation of medicines for many of the most common epidemics in Africa, including HIV/AIDS."

According to activists, (from the Treatment Action Movement of Nigeria, AIDS Alliance Nigeria, Journalists Against AIDS Nigeria, and other organizations), the meeting to determine Nigeria's intellectual-property law is sponsored by the U.S. Department of Commerce -- and civil society in Nigeria has been kept out. Activists fear the new law could stop access to antiretrovirals in Nigeria, including the government's new program to make HIV treatment widely available.

"'It is outrageous that such an important meeting as one to draft an IP bill that will have implications on the fate of 3.5 million Nigerians living with HIV/AIDS, is being done without our input,' said Pat Matemilola, president of the Network of People living with HIV/AIDS in Nigeria (NEPWHAN). 'Considering the great import of decisions that would emanate from this meeting as regards continued access to life-saving treatment, we feel that our lives are being jeopardized by this omission. We demand that the conveners of this meeting call us to the table. Our lives must not be toyed with.'"

(The quotations above are from a November 18 press alert from the Treatment Action Movement.)

Marijuana Lung Health Report: Less Than Meets the Eye?

by John S. James

On or around November 12 the British Lung Foundation made news in England, the U.S., and probably around the world by releasing a report implying that marijuana smoke is more harmful than tobacco smoke in causing lung and other cancers and infections. The report, nine pages of text plus 90 references, is available at http://www.lunguk.org/news/a_smoking_gun.pdf

We found the "shocking new report" (quote from the British Lung Foundation Web site) more interesting for what did not make the news than for what did:

* This report was based on no new information -- only a re-telling of what was already published. It could have been produced and released at any time. (We could not find any date on the paper, incidentally, except for a 2002 copyright notice on the picture of a marijuana leaf. The press release accompanying the report on the Web was also undated, as of November 18.)